JAN 31 2002

K012727

510 k Safety and effectiveness summary

1. Carl Zeiss Ophthalmic Systems, Inc.
   Humphrey Division
   5160 Hacienda Dr.
   Dublin, CA 94568
   Contact Person – Melissa R. Horne
   November 2, 2001

2. Humphrey Optical Coherence Tomographer 3

3. We are claiming substantial equivalence to the Humphrey Optical Coherence Tomographer, the Heidelberg Retinal Tomograph, and the GDx by Laser Diagnostic Technologies.

4. In order to understand the Humphrey version of the Optical Coherence Tomographer. You must understand how Optical Coherence Tomography works. In general OCT Scanners permit the user to obtain and analyze cross-sectional tomograms of ocular tissue in a non-contact and non-invasive manner. The Humphrey Optical Coherence Tomography Scanner measures optical reflectivity to obtain cross sectional tomograms of the eye.

   The Humphrey OCT employs the principle of low coherence interferometry based upon the Michelson interferometer. In a Michelson interferometer, the light from a source is split into a sample path and a reference path containing a mirror. Light reflected back from the sample path and the reference path will create an interference pattern on a detector if the optical path lengths between the reference and sample are identical. Adjusting the length of the reference path will allow a semi-transparent sample, such as the retina, to be cross-sectionally scanned.

   The Super-Luminescent Diode (SLD) used in the Humphrey OCT Scanner permits a short coherence length in air. Accounting for the index of refraction of the eye, this translates to an even shorter coherence length within the retina. The SLD emits near infrared light which is scattered by the various interfaces and structures of the retinal tissue. As the reference arm is moved, a depth profile of the retina is produced which is similar to ultrasound A-scan. The profile plots variations in optical reflectivity between the different layers of the retina. Two mirrors mounted to galvanometers deflect the SLD beam within the eye. Scanning the retina in this manner produces cross-sectional images similar to ultrasound B-scan but of much higher resolution. The tomographic images of the retina produced by the OCT scanner provide an important tool in the diagnosis of retinal disorders and diseases that manifest themselves in the posterior pole of the eye.

5. This device will be used in the same manner as all OCT scanner devices. The Humphrey OCT is a safe and effective tool for the imaging and measurement of ocular structures. Previous submissions to the FDA, various publications, and clinical studies from independent researchers have demonstrated the efficacy of the OCT scanner. Independent analysis by an internationally recognized expert is included in this report and previous FDA submissions have demonstrated its safety. The information summarized below refers directly to the ability of the OCT to image and measure ocular structures.

The reproducibility of OCT measurements for RNFL and retinal thickness has been tested by numerous clinical trials. Among them, Konno and Akiba et al (2001) reported the ability of the OCT to reproduce quantitative information on foveal thickness and Blumenthal et al (2000) reported that RNFL measurements were reproducible for both normal and glaucomatous eyes.

Zangwill (2000) reports that the increased detection of RNFL damage by the OCT, improves early glaucoma detection. Shuman et al (1995) have reported their use of the OCT for monitoring glaucoma. Circular OCT scans at various radii centered around the optic nerve head (ONH) presented nerve fiber layer (NFL) thickness in the OCT image, which could be measured by analysis of the data. The NFL thickness measurement correlated with the RNFL drop out observed in ONH photographs and with visual field defect documented with visual field tests in glaucoma patients.

In a study of 78 patients, Hoh and Greenfield, et al (2000), correlated retinal nerve fiber layer structural measurements with visual function. They report that they were able to differentiate between non glaucomatous and glaucomatous eyes using the OCT. Bowd and Zangwill (2001) report the ability to detect early glaucoma by the assessment of retinal nerve fiber layer using the OCT. In the same study, comparing the ability of different methods of detecting early glaucoma by assessment of retinal nerve fiber layer thickness, concluded that the OCT was more sensitive than standard automated perimetry or scanning laser polarimetry.

Reporting in the Archives of Ophthalmology, Zangwill and Bowd (2001), studied the ability of the OCT to discriminate between normal healthy eyes and eyes with early to moderate glaucomatous visual field loss. Qualitative assessments of stereo photographs and OCT measurements had no significant differences in sensitivities.

A safety analysis was performed by an independent consultant, who is an internationally recognized expert in the field of optical radiation hazards and safety, in order to determine if the energy introduced into the eye by the OCT scanner poses any safety risk.
The safety analysis concludes that the device under normal operating circumstances would never exceed the limits for human ocular exposure.

The maximum output power of the IR LED is well below the continuous ACGIH/ICNIRP limit of 2mW.

6. The OCT3 is substantially equivalent to the predicate device. One of the differences between the two devices are that the new OCT combines many of the separate components utilized into one more cohesive unit. The devices are very similar in materials and energy source. The new OCT has an increased scan rate for high resolution scanning.

References

Schuman JS, Hee MR, Puliafito CA, Wong C, Pedut-Kloizman T, Lin CP, Hertsmark E, Izatt JA, Swanson EA, Fujimoto JG. Quantification of nerve fiber thickness in normal and glaucomatous eyes using optical coherence tomography; a pilot study. *Archives of Ophthalmology* 1995; 1130:586-596

Konno S, Akiba J, Yoshida A. Retinal thickness measurements with optical coherence tomography and the scanning retinal thickness analyzer. *Retina* 2001; 21(1): 57-61

Blumenthal EZ, Williams JM, Weinreb RN, Girkin CA, Berry CC, Zangwill LM. Reproducibility of nerve fiber layer thickness measurements by optical coherence tomography. *Ophthalmology* 2000; Dec; 107(12): 2278-82

Hoh ST, Greenfield DS, Mistlberger A, Liebmenn JM, Ishikawa H, Ritch R. Optical coherence tomography and scanning laser polarimetry in normal, ocular hypertensive, and glaucomatous eyes. *American Journal of Ophthalmology* 2000; Feb; 129(2):129-35

Bowd C, Zangwill LM, Berry CC, Blumenthal EZ, Vasile C, Sanchez OC, Bosworth CF, Sample PA, Weinreb RN. Detecting early glaucoma by assessment of retinal nerve fiber layer thickness and visual function. *Investigative Ophthalmology and Visual Science* 2001 Aug;42(9):1993-2003

Zangwill LM, Williams J, Berry CC, Knauer S, Weinreb RN. A comparison of optical coherence tomography and retinal nerve fiber layer photography for detection of nerve fiber layer damage in glaucoma. *Ophthalmology* 2000 Jul;107(7):1309-15

Zangwill LM, Bowd C, Berry CC, Williams J, Blumenthal EZ, Sanchez-Galena CA, Vasile C, Weinreb RN. Archives of Ophthalmology 2001 Jul;119(7):985-93

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2002

Ms. Melissa R. Horne
Associate Product Manger, OCT
Carl Zeiss Ophthalmic Systems, Inc.
5160 Hacienda Drive
Dublin, California 94568

Re: K012727
Trade/Device Name: Optical Coherence Tomography Model 3000 (OCT 3)
Regulation Number: 21 CFR 892.1560; 886.1570
Regulation Name: Ultrasonic pulsed echo imaging system and Ophthalmoscope
Regulatory Class: II
Product Code: IYO; HLI
Dated: October 31, 2001
Received: November 5, 2001

Dear Ms. Horne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K012727

Device Name: Humphrey OCT 3

Indications For Use: The Humphrey OCT3 is a high resolution tomographic device for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for in vivo imaging and measurement of the retina, retinal nerve fiber layer and optic disk. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema, central serous retinopathy and glaucoma.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K012727

(Optional Format 3-10-98)